UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

TAKEDA CHEMICAL INDUSTRIES, LTD. and TAKEDA PHARMACEUTICALS, NORTH AMERICA, INC., Plaintiffs,	03 Civ. 8253 (DLC)
-v-	OPINION AND ORDER
MYLAN LABORATORIES, INC. and UDL LABORATORIES, INC., Defendants.	

Appearances:

For Takeda Chemical Industries, Ltd. and Takeda Pharmaceuticals North America, Inc. (collectively "Takeda"):
David G. Conlin
Barbara L. Moore
Edwards & Angell, LLP
101 Federal Street
Boston, MA 02110-1800

For Mylan Laboratories, Inc., Mylan Pharmaceuticals, Inc., and UDL Laboratories, Inc. (collectively "Mylan"):
Martin B. Pavane
Mindy H. Chettih
James P. Doyle
Cohen, Pontani, Lieberman, & Pavane
551 Fifth Avenue
New York, New York 10176

DENISE COTE, District Judge:

On July 7, 2005, Mylan moved for reconsideration, pursuant to Local Civil Rule 6.3, of this Court's June 21, 2005 Memorandum Opinion and Order ("June 21 Order") precluding Mylan from

offering at trial any evidence as to the invalidity of U.S. Patent No. 4,687,777 (the "'777 Patent") except that based on a theory of obviousness as set forth in its September 8, 2003 Notice of Paragraph IV certification to Takeda. Mylan has abandoned the theory of obviousness identified in its Pargraph IV certification and after the close of fact discovery has sought to substitute a new theory. For the reasons stated herein, Mylan's motion for reconsideration is denied.

Background

On September 8, 2003, Mylan sent Takeda a Notice of Paragraph IV Certification, in which it informed Takeda that it had submitted an Abbreviated New Drug Application ("ANDA") regarding the sale of pioglitazone before the expiration of certain patents ("September 8 Notice"). That notice described Mylan's belief that the '777 patent was invalid on the basis of obviousness due to Compound 16 of U.S. Patent No. 4,287,200 (the "'200 Patent"), which Mylan asserted is identical to a Compound 14 identified in a prior publication authored by Dr. Sohda (the "Sohda article").[1]

In January of this year, in response to a 30(b)(6) notice

[1] This publication is Sohda et al., Studies on Antidiabetic Agents.II.Synthesis of 5-[4-(1-;Methylcyclohexylmethoxy)-benzyl]thiazolidine-2,4-dione (ADD-3878) and Its Derivatives, Chem. Pharm. Bull. Vol. 30(10)-3580-3600 (1982).

from Takeda, Mylan identified three persons as knowledgeable with respect to its claim that the '777 patent is invalid on the basis of obviousness: Dr. John O'Donnell, Mylan's chief scientific officer; Wayne Talton, Mylan's head of regulatory affairs; and Shelly Monteleone, a patent attorney who works at Mylan. Dr. O'Donnell remains unable to testify due to medical reasons, and although both Talton and Monteleone were deposed, neither one furnished relevant testimony regarding the factual and/or scientific bases for Mylan's Paragraph IV certification.

As a result, on March 17, 2005, Takeda served contention interrogatories on Mylan, in which it requested that Mylan identify "every claim of the Takeda Patents" that Mylan contends is not valid or is unenforceable and that Mylan provide "[a] complete explanation of [its] basis for its contention that each such claim is not valid or is unenforceable." Takeda also served a second 30(b)(6) notice on Mylan on April 13, 2005 that explicitly requested that Mylan produce a witness to testify to "[e]ach and every basis upon which [Mylan] contend[s] or will contend that [the '777 Patent] is invalid, unenforceable, or will not be infringed (whether or not such basis is contained in the Paragraph IV Certification)" as well as to "[e]ach and every fact supporting or undermining" these bases. These two issues constituted Topics 6 and 7 of Takeda's 30(b)(6) notice.

On April 25, Mylan responded to Takeda's contention

interrogatories and did not mention any basis for a claim of obviousness with respect to the '777 Patent. Instead, it stated for the first time that the '777 Patent is unenforceable due to Takeda's lack of good faith and candor in applying to the Patent and Trademark Office for that patent.[2] Several days later, on April 29, 2005, Mylan completed its objections to the April 13 30(b)(6) Notice. In these objections, Mylan refused to respond to Topics 6 and 7 on the grounds that the information sought was protected by the attorney-client privilege and work-product immunity and that Takeda instead should seek to discover the bases for Mylan's claims of invalidity or unenforceability of the '777 Patent through contention interrogatories. Subsequently, Takeda and Mylan engaged in unsuccessful negotiations as to the timing of the 30(b)(6) deposition.

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[2] In relevant part, Mylan's response reads as follows:

> Mylan responds that every claim of the '777 patent is unenforceable. The named inventors of the '777 patent and/or one or more other persons under a duty of candor to the PTO made affirmative misrepresentations of material fact, failed to disclose material information and/or submitted false material information in the application which issued as the '777 patent and in the Amendment and Declaration submitted to the PTO on November 25, 1986, all of which information would have been considered important to the Patent Examiner in deciding whether to allow the application to issue as the '777 patent. Such affirmative misrepresentations, failures to disclose material information and submissions of false material information were done with intent to deceive the Patent Examiner so as to induce the PTO to issue the '777 patent.

Given the parties' inability to agree upon an appropriate time for this deposition, as well as the parties' continuing debate about the scope of that deposition and Dr. O'Donnell's ability to testify, a May 25 telephone conference, which was held on the record, addressed these issues, inter alia. During that conference, it was noted that Mylan had not complied with the Court's prior instructions regarding the scheduling of depositions. The Court further recounted that per the parties' consent, Mylan was required to produce a 30(b)(6) witness and that that witness was required to "have, as part of the preparation for that deposition, a meeting with Dr. O'Donnell to obtain all relevant information necessary to respond fully and completely to the 30(b)(6) deposition" notice. (Emphasis added.)[3]

On June 2 and 3, Takeda deposed Brian Roman ("Roman"), Mylan's designated 30(b)(6) witness. Despite the Court's May 25 Order, Roman did not testify to Topics 6 and 7 during his deposition. Although Roman was asked whether the paragraph IV certification "contain[s] all of the reasons why Mylan contends that the claims of the '777 Patent are invalid or unenforceable of which it was aware on or before September 8, [2003]," counsel for Mylan instructed him not to answer the question. Roman did

[3] The Court also ordered during the May 25 telephone conference that Dr. O'Donnell may not submit "an affidavit in connection with summary judgment practice or appear[] as a trial witness unless he was produced for a deposition" before the May 27, 2005 close of fact discovery.

respond, however, to questions regarding various compounds identified in the Sohda article. When asked whether several compounds, including Compound 57, in the Sohda article would be deemed to be a compound of interest to "one of ordinary skill in the art," Roman explained that "if one were looking for a compound that had an acceptable toxicity profile as well as the types of activity that one's looking for here," the body weight and fat weight increases associated with compounds 57 and 58 "should cause one to rule that out."

On June 6, 2005, three days after Roman's deposition, Mylan served supplemental responses to Takeda's contention interrogatories. In these supplemental responses, Mylan asserted for the first time that the '777 Patent is invalid as obvious on the basis of Compound 57 of the Sohda article, which is equivalent to Compound 40 of the '200 Patent and to which Mylan assigns the shorthand "2-pyridal derivative".[4] According to Mylan's supplemental response, "[p]ioglitazone is an obvious modification of the 2-pyridal derivative, which the prior art teaches possesses hypolipidemic and hypoglycemic activities with low toxicity. Pioglitazone is not unexpectedly different in

[4] Mylan asserts that Compound 57 of the Sohda article is the same as that compound "denominated by Takeda as compound 3894." This Opinion refers to this compound as Compound 57.

activity or toxicity from the 2-pyridal derivative."[5]

By way of a June 14, 2005 letter, in which it described much of the above history, Takeda argued that Mylan had been "playing a shell game" with respect to its attack on the '777 Patent and requested that this Court enter an Order precluding Mylan from introducing at trial any evidence as to invalidity of the '777 Patent except based on obviousness "as expressly set forth in the Detailed Legal and Factual Basis for Certification which Mylan sent to Takeda on September 8, 2003." A conference in this action was held on that day, during which the parties principally discussed the evidentiary bases for Mylan's motion for leave to amend its answer to assert a claim of inequitable conduct and whether prejudice would result from the granting of the motion. Noting that Mylan had identified two late-disclosed documents, as well as related deposition testimony, that might support an inequitable conduct claim, that motion was granted through a June 15, 2005 Order.

Toward the end of the June 14 conference, however, the Court asked Mylan's counsel to address Takeda's June 14 letter. Counsel stated that he understood "the nature of our allegation on obviousness [to be a] purely legal argument, possibly supplemented with some expert scientific testimony." Counsel

[5] In contrast to the detailed analysis contained in its Paragraph IV certification, Mylan's June 6 notification regarding Compound 57 was remarkably vague.

further argued that 35 U.S.C. § 282 "provides for a deadline some point prior to the trial at which a defendant must identify all prior art to be cited against the patent. Up until that time, not only can you add new arguments and new theories, you can add new references to be asserted against the patent." Takeda's counsel disagreed, contending that the law does not allow an ANDA applicant to change its theory. Given this disagreement, the June 15 Order provided that Mylan's reply to Takeda's June 14 letter was due on June 16, and that Takeda's reply was due on June 17.

In its June 16 letter, Mylan contested Takeda's request for an order of preclusion on several grounds. First, Mylan asserted that where an ANDA applicant attacks a patent claim on the basis of obviousness under 35 U.S.C. § 103, "[e]xpert opinion is relied upon to establish whether a person of ordinary skill in the art to which the patent pertains would have found the invention to be obvious in view of the prior art." Mylan further stated that in pursuing its claim that the '777 claim was invalid, it would "not rely on information or testimony from Mylan or any of its employees" but would instead provide "the detailed bases for Mylan's invalidity arguments" in its expert reports. As a result, it argued, Takeda could not claim to be prejudiced by its June 6 responses.

With respect to whether or not Roman was obligated to

testify as to Topics 6 and 7 of Takeda's 30(b)(6) notice, Mylan noted that it had objected to these topics and that Takeda had not addressed them in a letter to the Court. It further noted that Roman could not have provided testimony regarding Topics 6 and 7 of Takeda's 30(b)(6) notice because prior to June 6, neither Roman nor any other Mylan employee possessed "non-privileged information responsive to [these topics] regarding any of Mylan's invalidity contentions other than those set forth in the Detailed Statement that Mylan provided to Takeda in September, 2003." With respect to Roman's testimony regarding Compound 57, Mylan contended that as Roman is "not a person of ordinary skill in the art to which [the '777 Patent] pertains," his statements about such prior art were irrelevant to this action. Finally, Mylan's June 16 response cited only one case, Smithkline Beecham Corp. v. Apotex Corp., No. 98 C 3952, 2000 WL 116082 (N.D. Ill. Jan. 24, 2000), which it stated stood for the proposition that it should not be held to the theories set forth in a notice letter.

It is unnecessary on this motion to summarize Takeda's June 17 reply, which primarily disputed Mylan's reading of Smithkline Beecham and argued that Mylan's changing its theory of obviousness would exert "palpable" prejudice on Takeda, in any detail. It should be noted, however, that like Mylan, Takeda relied on little case law in its letter briefs on this issue.

Takeda's June 14 letter contained no case law, and aside from discussing Smithkline Beecham, Takeda's June 17 letter presented only one other case, ATD Corp. v. Lydall, Inc., 159 F.3d 534 (Fed. Cir. 1998).

Discussion

Local Civil Rule 6.3 reads in pertinent part as follows:

> A notice of motion for reconsideration or reargument shall be served within ten (10) days after the docketing of the court's determination of the original motion. There shall be served with the notice a memorandum setting forth concisely the matters or controlling decisions which counsel believes the court has overlooked.

S.D.N.Y. Local Civil Rule 6.3. In moving for reconsideration, the moving party "must demonstrate that the court overlooked controlling decisions or factual matters that were put before it on the underlying motion." Eisemann v. Greene, 204 F.3d 393, 395 n.2 (2d Cir. 2000) (citation omitted). In addition, the moving party may not "advance new facts, issues, or arguments not previously presented to the Court." Geneva Pharm. Tech. Corp. v. Barr Labs., Inc., No. 98 Civ. 3607 (RWS), 2002 WL 1933881, at *1 (S.D.N.Y. Aug. 21, 2002) (citation omitted).

Courts narrowly construe Local Civil Rule 6.3 and apply it strictly against the moving party "so as to avoid repetitive arguments on the issues that have been considered fully by the court" and "to prevent the practice of a losing party examining a

decision and then plugging the gaps of a lost motion with additional matters." Mones v. Commercial Bank of Kuwait, No. 18 Misc. 302 (SAS), 2005 WL 1963955 (S.D.N.Y. Aug. 11, 2005), at *2 (citation omitted). The decision to grant or deny the motion is within the sound discretion of the district court. See Devlin v. Transp. Communications Int'l Union, 175 F.3d 121, 132 (2d Cir. 1999).

Mylan contends that the June 21 Order overlooked the fact that Mylan "could not possibly have developed" its obviousness defense based on Compound 57 "until after Takeda's belated production of critical comparative data." Mylan asserts that "the evidence of similar activity and toxicity upon which Mylan's [obviousness] defense is based are derived solely from data in Takeda's document production" that Mylan did not receive in unredacted form until February, March, and April 2005. This argument is entirely unavailing. At no point during the June 14 conference or in its June 16 letter did Mylan discuss any of the evidentiary bases for its obviousness defense with respect to the '777 Patent, much less contend that Takeda's delay in producing unredacted versions of any documents was the reason that Mylan waited until June 6 to assert such a defense.[6]

[6] To the extent Mylan seeks to explain this omission by reference to the fact that letters to the Court are subject to a two-page limit, that explanation can be swiftly rejected. As the parties to this litigation well know, whenever their correspondence indicates that further explication of an issue is

Yet even if Mylan had presented these facts in opposing Takeda's request, Mylan's argument is fundamentally flawed. At the June 14 conference, in the context of justifying Mylan's delay in asserting its inequitable conduct claim, counsel for Mylan represented that although compound 3894 was "expressly identified" in a prior art publication, it was not until receiving the unredacted version of an internal Takeda report labeled A-15-34 on February 4, 2005 that Mylan understood that Takeda failed to report to the PTO that its internal research demonstrated that "pioglitazone was not so superior" to this compound. Mylan's counsel further stated that Takeda's production of this data "would have led the examiner to understand that you can't patent pioglitazone because it's not different than what was in the prior art." Yet even accepting that Mylan did not obtain an unredacted version of A-15-34 until February 2005, a patentee's internal data is irrelevant to a claim of invalidity on the basis of obviousness. As the Federal Circuit has explained, and as Takeda points out in its opposition brief, an invention is obvious when a person of ordinary skill in the prior art would have expected a particular result given the

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necessary, the Court schedules conferences or permits briefing to give them an opportunity to develop their argument. One such conference was held on June 14, and the June 16 letter could have alluded easily to the discussion at the June 14 conference of the unredacted documents if that were helpful to explain Mylan's tardy disclosure of the new theory of obviousness.

"knowledge already available in the art at the time" of the patentee's invention. In re Merck & Co., Inc., 800 F.2d 1091, 1096 (Fed. Cir. 1986) (emphasis supplied).

In its reply, Mylan does not contest Takeda's description of the law of obviousness. Nor does Mylan challenge Takeda's assertions that Mylan has had all of the pertinent prior art in its possession for at least two years and that Mylan has had "all" of the Compound 57 test data relied on by Mylan's expert in his recently produced expert report since the summer of 2004. Instead, Mylan shifts its argument and now claims that it could not have asserted that the '777 Patent is obvious on the basis of Compound 57 until "completing discovery on all bases on which Takeda might argue the unexpected superiority of pioglitazone over [Compound 57]." Mylan further argues that given that patent holders may introduce into evidence any "work done in studying the invention," even if not included in the patent application, in response to a litigation attack on the patent's validity, Knoll Pharm. Co., Inc. v. Teva Pharm. USA, Inc., 367 F.3d 1381, 1385 (Fed. Cir. 2004), its own prolonged investigation was "perfectly appropriate." That the law allows patent holders to respond to attacks on a patent's validity by using data not in the prior art has no bearing on what showing Mylan must make to prove invalidity on the basis of obviousness in the first instance and is therefore beside the point.

Mylan next argues that the June 21 Order improperly relied on certain facts regarding Roman's deposition. Specifically, Mylan deems erroneous that portion of the Order that notes that Mylan's counsel's objected to questions "as to the basis for Mylan's contentions that the '777 Patent is invalid, unenforceable, or not infringed, other than those disclosed in the September 8 Notice" on the basis of the attorney-client and work-product privileges. According to Mylan, its counsel's objections were proper as Mylan not only "made clear in advance of the deposition" that it would not produce a fact witness on Topics 6 and 7, but also because Mylan would have violated the protective order in this case had it shared with Roman the highly-confidential "activity and toxicity data" upon which Mylan's claim of obviousness based on Compound 57 hinges. Since a claim of obviousness must be based on publicly available knowledge, Mylan's contention that it would have violated a protective order to respond to this question is specious. In any event, the description of Roman's deposition is ancillary to the analysis underlying the June 21 Order.

Finally, Mylan argues that the June 21 Order incorrectly applied ATD Corp. v. Lydall, Inc., 159 F.3d 534 (Fed. Cir. 1999), by failing to consider carefully whether Takeda has been prejudiced by Mylan's belated disclosure of its defense that the '777 Patent is obvious on the basis of Compound 57. In Lydall,

the Federal Circuit examined whether the district court appropriately exercised its discretion to preclude the defendant from relying on a prior art reference first disclosed to the plaintiff three months after the close of discovery. Although the plaintiff argued that pursuant to 35 U.S.C. § 282, a party may disclose the prior art upon which it relies for an assertion of invalidity on the basis of obviousness until thirty days prior to trial, the Lydall court disagreed, holding that where "a specific judicial directive for the timing of discovery" has been set, that procedure, and not 35 U.S.C. § 282, "necessarily governs that trial" and "establishes the procedure to which the parties are bound." Id. at 551. In so holding, the Lydall court noted that the purpose of both Section 282 and the Federal Rules of Civil Procedure is "to prevent unfair and prejudicial surprise, not to facilitate last-minute production of evidence." Id. Nevertheless, at no point does Lydall require a district court to make a finding of prejudice in order to preclude a theory not made available to the other side during the discovery period.

Even if Lydall compels a district court to find that the party seeking preclusion has been prejudiced, Mylan's claim that Takeda will suffer no prejudice by virtue of its change in theories is wrong. According to Mylan's June 16 letter, Takeda will not be surprised at trial because Mylan will disclose "the

bases for Mylan's invalidity theories" during expert discovery. Allowing Mylan to assert a new theory of obviousness, based on Compound 57, and to elaborate upon this theory through expert discovery will require an alteration of the expert discovery schedule. In addition, Takeda would be entitled to reopen fact discovery to investigate why Mylan believes that the '777 Patent is obvious in light of Compound 57. As Roman's deposition testimony demonstrates, appropriate questioning in fact discovery can undermine Mylan's obviousness theory. Especially given that the parties have been repeatedly warned that their January 2006 trial date is firm, requiring Takeda to revisit its expert and fact discovery in order to give it a fair opportunity to respond to Mylan's newly asserted theory would result in "palpable" prejudice to Takeda. For all of the above reasons, Mylan's motion for reconsideration of the June 21 Order is denied.

Conclusion

Mylan's motion for reconsideration of the June 21 Order precluding Mylan from introducing at trial "any evidence as to the invalidity of the '777 Patent except based on a theory of obviousness set forth in the September 8 Notice" is denied.

SO ORDERED:

Dated: New York, New York
August 31, 2005

DENISE COTE
United States District Judge